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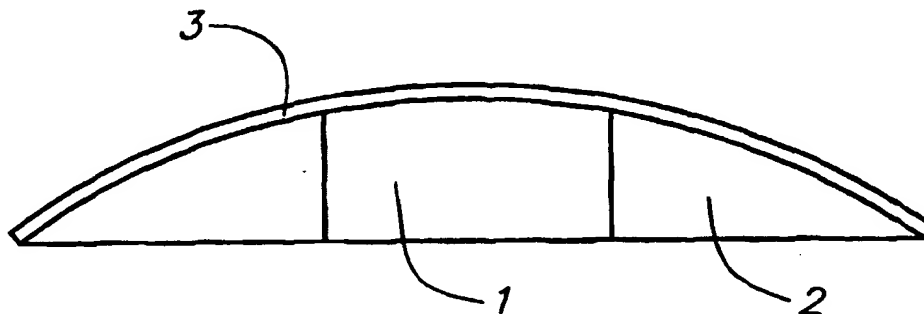
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(54) Title: A PRESSURE RELIEVING DRESSING



(57) Abstract

A pressure relieving dressing comprising an absorbing element and a substantially non-absorbing pressure distributing element, in which the absorbent element constitutes a part of a proximal skin contacting surface, said absorbing element being encircled by the pressure distributing element or being situated at the border of the pressure distributing element constituting the remaining part of the surface of the dressing to be in contact with the skin rendering it possible to obtain an effective and durable dressing suitable for both wound healing and prophylaxis of pressure ulcers.

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TITLE

A pressure relieving dressing

FIELD OF THE INVENTION

The present invention relates to a pressure relieving dressing used for prophylaxis or treatment of ulcers as well as for protection of fragile skin.

BACKGROUND OF THE INVENTION

Many people, especially diabetics, who suffers from long term complications such as ischeamia and neuropathy or patients confined to their bed are known to develop ulcers on foot, hip or sacrum. Foot ulcers are usually located on the plantar or on the side or dorsum of the foot. Foot ulcers are induced by changes in bone structure, which can lead to protruding prominences and reduced thickness of the subcutaneous layer that ensures distribution and relief of the pressure applied to the foot.

The development of foot ulcers are i.e. dependent on a combination of etiology and the induction of pressure. There are essentially two mechanical inducers for pressure sore development, the stress of permanent (static) pressure and the stress of short term (dynamic) pressure.

The permanent or static pressure is when exertion of pressure over a long period (hours typically) is leading to the risk of collapse of veins and arteries. The collapse of these blood vessels may lead to ischemia e.g. lack of oxygen and nutrition and a build up of waste materials. These events may eventually lead to development of ulcers. The tendency is the longer period of pressure induction, the lower pressure is critical and may cause damage.

Short term or dynamic pressure impact is in the form of repetitive mechanical stress. This occurs e.g. when walking, where a typical pre-stage to ulceration is callus build-up. This type of ulceration may be compared to benign sanguinous blister formation. Critical pressure level of this type of pressure impact is much
5 higher than in the case of a long time pressure load.

Dressings designed to manage wound healing and exudate are well known in the art. However, they do not take into account the effects of the pressure stress.

From International Patent application No. WO 91/01706 A1 (Smith & Nephew) is known a polymeric foam absorbent dressing for exudate handling in wound
10 healing. No pressure relief/distribution properties are mentioned. This dressing comprises a foam material all over the surface. Since this open cell foam is designed to allow transportation of exudate, it has inadequate strength towards pressure, and will be compressed or collapse when worn on a foot.

WO 99/01166 A1 (Coloplast A/S) discloses a non-fibrous polysaccharide wound
15 dressing capable of handling wound exudate by gelling properties. This material is very soft and gentle towards the ulcer. However, it has inadequate strength towards mechanical pressure and will collapse if pressure is applied.

Examples of pressure reducing/distributing/shock-lowering orthopaedic materials and products are also known:

20 In international Patent application No. WO 90/09746 A1 (Bernard, M.) is disclosed a composite inner sole for sports shoes, comprising a shock absorbing layer. No wound healing or exudate absorbing properties are mentioned.

US Patent No. 5 488 786 (Ratay, E.J.) discloses a highly resilient insole, designed to cover the whole sole of the shoe i.e. the whole plantar surface of the foot. No wound healing or exudate absorbing properties are mentioned.

Only few examples of a combining the two said properties are known:

- 5 From DE patent application No. 35 39 533 (Liedtke) is known a foam dressing. The dressing comprises a foam body, the non-skin-contacting surface optionally being covered with a film and the outer periphery of the skin-contacting edge covered with an adhesive. The foam serves both as a pressure reducing and distributing element and as an absorbing element. Between the adhesive-
- 10 covered edge and the non-adhesive central part is a groove in the foam, as well as more grooves or indentations may appear in the central part. These grooves are made to enhance the flexibility of the dressing. The dressing is made of a single piece of foam, and the only barriers to control the wound exudate is the top film and the adhesive, leaving a severe risk of maceration when used on
- 15 exuding wounds. In one embodiment of the invention, the dressing comprises a slit in the foam defining a lid to be opened and an absorbing pad may be inserted over the wound. However, this construction with a slit may give rise to problems with leakage.

- GB patent No. 842 847 (Scholl) discloses a corn dressing, comprising a foam
- 20 ring, serving as a pressure distributing part and a thinner central part with a napped inner side having a shock absorbing/cushioning effect. In the cavity between the central part and the skin/treated area a pad with medication may be placed. The reference is silent with respect to wound treatment as well as use of absorber, on the contrary, the device is donating medication to the treated site.

International Patent application No. WO 93/01777 A1 (Malloul, L.) discloses a dressing for sutured wounds. Said dressing has a foamed shock-absorbing element or cushion layer on both sides of the wound, protecting the wound from impact or pressure, and an area spaced apart from the wound with a pad right
5 over the wound. The dressing only copes with dynamic pressure in the form of sudden impacts, and is silent with respect to static pressure.

European Patent No. EP 0 164 319 (Coloplast A/S) discloses a wound dressing of the hydrocolloid type with a pressure relief system of foam. The pressure is distributed through the foam in order to relieve the pressure on the ulcer. The
10 dressing offers a possibility to adapt a specific relief area corresponding to the size of the ulcer, rendering it possible to transfer the pressure from the wound site to the surrounding healthy tissue. The pressure relief is described as having static pressure relieving properties, not dynamic pressure/shock relieving properties.

15 Diabetic patients are often suffering from neuropathy, rendering their sensibility skills to be greatly diminished or they may even suffer from a complete loss of feelings in the lower extremities, and especially in the feet. The patient will often fail to notice or be aware when individual points of a foot are subjected to severe constant pressure or repetitive stress, for example during long periods of stand-
20 ing or by use of badly fitting shoes, inducing the development of an pressure sore. Since metabolism is disturbed and blood circulation already can be reduced in diabetes patients, healing of such sores is most difficult.

Attempts have been made to prevent the development of pressure sores and ulcers in a patient who might not be able to recognise presence of severe sore
25 inducing condition.

Dressings with different kinds of indicators are known, e.g. from European Patent application No. 430 608 (E. R. Squibb & Sons, Inc.), which discloses a wound dressing comprising a temperature sensing liquid crystal tape, affixed to the backing layer. A temperature change may indicate a change in wound condition.

- 5 In the reference is also mentioned the possibility of a pressure indicator in the form of a piezoelectric element.

- US Patent No. 5 642 096 (Paromed Medizintechnik GmbH) discloses a device for prevention of ulcers on the feet of diabetic patients. The device includes a pressure and temperature sensor in the form of a piezoelectric element carried in
- 10 the innersole of the shoe. The patient is warned by a signal, e.g. a buzz if the pressure reaches a critical level. The device is constricted to the innersole of the shoe, and does not cope with detecting impacts to other body parts e.g. the side of the foot or on hips or sacrum, and it is also technically complicated and expensive.

- 15 Until now a dressing being capable of both handling wound exudate and at the same time relieving both static and dynamic pressure has not been disclosed.

- It has now surprisingly been found that the above mentioned problem can be overcome by combining a shock-absorbing material with a moisture-absorbing material rendering it possible to obtain an effective and durable dressing suitable
- 20 for both wound healing and prophylaxis of pressure ulcers as well as for protection of fragile skin.

BRIEF DESCRIPTION OF THE INVENTION

- The present invention relates to a pressure relieving dressing comprising an absorbing element and a substantially non-absorbing pressure distributing
- 25 element.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is explained more in detail with reference to the drawings in which:

Figure 1 shows a top view of an embodiment of the invention.

Figure 2 shows another embodiment of the invention.

5 Figure 3 shows a cross-section of an embodiment of the invention.

Figure 4 shows a cross-section of another embodiment of the invention.

Figure 5 shows a cross-section of yet another embodiment of the invention.

Figure 6 shows a cross-section of a still further embodiment of the invention.

Figure 7 shows a cross-section of yet another embodiment of the invention.

10 Figure 8 shows a still further embodiment of the invention seen from above.

DETAILED DESCRIPTION OF THE INVENTION

The invention relates to a pressure relieving dressing comprising an absorbing element and a substantially non-absorbing pressure distributing element, which dressing is characterised in that the absorbent element constitutes a part of a

15 proximal skin contacting surface, said absorbing element being encircled by the pressure distributing element constituting the remaining part of the surface of the dressing to be in contact with the skin.

The invention further relates to a pressure relieving dressing comprising an absorbing element and a substantially non-absorbing pressure distributing

20 element, characterised in that the absorbent element constitutes a part of a proximal skin contacting surface, said absorbing element being situated at the border of the pressure distributing element constituting the remaining part of the surface of the dressing to be in contact with the skin.

In order to prevent the development of ulcers and/or enhance the healing of

25 ulcers a combination of an absorbing element and a pressure distributing and

pressure shock-absorbing element has been shown to be advantageous. The absorbing element is able to handle exudates from a wound and provide the optimal environment for wound healing, while the pressure distributing element will work as a shock absorber and a pressure distributing element and diminish
5 further damage to the wound area.

By using a substantially non-absorbing pressure distributing element this will serve as a barrier to the wound exudate as well as the properties of the element will not change due to absorption of wound exudate.

The dressing according to the present invention reduces the impacts from
10 pressure shocks to the selected body part, and offers pressure distributing properties of susceptible areas. These properties are important both in the prophylactic phase as well as in the treatment of an ulcer or protection of the former wound site after healing. The absorbing element of the dressing of the invention is preferably more compressible than the pressure distributing element
15 covering the area next to the treated areas and in that way reducing the direct pressure on the wound.

The combination of an absorbing element combined with an pressure distributing element ensures that no changes in properties of the dressing due to long term pressure is observed. The dressing of the invention can be in the form of a very
20 flexible, thin device of a size rendering it suitable for wearing in shoes without discomfort.

The principles of pressure distributing is to transfer a (too) high pressure from a high risk area to a larger area, preferably an area located proximal or bilateral to the threatened area.

This is often achieved by drawing a ring of pressure distributing material with the high risk area in the centre. However, by isolating the high risk area behind a heavy barrier of pressure distributing material, the high risk area will be locked up inside the ring, giving rise to problems with the circulation of body fluids as well as a risk of developing oedemas. By placing the pressure distributing material apart from the centre of the device, e.g. with the shape of a horseshoe maybe with the legs of the shoe connected by a thin piece of pressure distributing material, around the high risk area, a more open structure is achieved. The central piece of the horseshoe may preferably be in the end being first exposed to the pressure, e.g. if the dressing is worn on the heel, in the heel end, while the open end of the horseshoe is pointing towards the toes. In this way, the construction of the dressing may even enhance the circulation in the tissue of the high risk area.

In one embodiment of the invention the dressing may be substantially planar with circular or elliptical shape for use on e.g. heels. The absorbing element may preferably be situated at the periphery of the dressing.

In another embodiment of the invention the dressing may be in the form of a three-dimensional structure e.g. for use on toes.

The pressure distributing element is preferably an elastomer.

The pressure distributing element may comprise synthetic polymers such as silicones, polyurethanes, elastomeric copolymers or hydrophobic foams with designed properties or it may be a natural polymer such as natural rubbers.

The elastomer has great ability of distributing both the static pressure and the sudden impacts, and at the same time it is durable and does not collapse during use, but conserves its elasticity and shape.

Some elastomers are transparent, which may be an advantage when used in a
5 dressing according to the invention. A transparent or semi-transparent dressing will render it possible to watch the condition of the underlying skin or wound without removing the dressing.

In a preferred embodiment of the invention a water permeable elastomer is used, enabling water vapour transport through the dressing.

10 Foams are often used as pressure distributing materials. However, many foams may absorb liquid and change properties, by softening or even collapse.

It is preferred that the pressure distributing material does not significantly change pressure distributing properties when contacted with moisture or aqueous liquids, such as wound exudate and perspiration.

15 However, it may be advantageous to have a pressure distributing material being able to handle minor amounts of moisture. This can be achieved by incorporating an absorber in particular form in the pressure redistributing material.

In one embodiment of the invention the pressure distributing material comprises one or more indentations. The indentations may be in the form of holes, dots,
20 ribs or the like. The presence of the indentations will provide more flexibility to the dressing and, depending on the depths of the indentations they may also serve as diffusion points. The indentations may penetrate the pressure distributing material but not the top layer, if such is present.

Incorporation of a support material in the bandage may be advantageous. It may be in the form of a web or net, e.g. a non-woven or a nylon net. The support material may e.g. be situated at the proximal side of the dressing.

The product may be used both as an ulcer prophylaxis and as a wound dressing
5 for all kinds of pressure ulcers, such as foot ulcers, leg ulcers, hip ulcers and sacrum ulcers. The dressing may also be used as a protection of recently healed and thus still fragile skin.

The absorbent element may comprise a hydrophilic foam, such as polyurethane, silicone, styrene-butadiene, styrene-isoprene or a surface coated polyethylene,
10 or a water soluble or gelling biopolymers such as polysaccharides, e.g. alginates, polyvinyl-pyrrolidone gels or hydrocolloids.

Preferably the absorbent element is more compressible than the pressure distributing element.

The absorbent element may be located as discrete or connected zones in the
15 pressure distributing element, either penetrating the pressure distributing element from top side to the skin-contacting side of the element or only going partly through the dressing, with the open end towards the skin.

The absorbent element may be in the form of a pattern of interconnected zones.

The zones of the absorbent element may be of any shape, e.g. in the form of
20 dots, lines, squares or concentric circles.

The absorbing element is preferably situated excentrically with respect to the pressure distributing element.

In an embodiment of the invention the absorbent element may comprise more than one absorber, e.g. a foam part in the portion in contact with the skin, and on
5 top of the foam a super absorber part being capable of soaking the moisture from the foam and in this way remove excess moisture from the skin-contacting part.

It is preferred that the surface of the dressing to be brought in contact with the skin shows adhesive properties.

10 The device can be fully or partly covered with an adhesive on the skin-facing surface in order to attach the device to the wearers body-part, e.g. the plantar, heel or toes. Alternatively, the adhesive can be located on the non-skin facing side, and in this way attach the device to the innersole of the wearers shoe.

The adhesive may be coated to the surface of the dressing in the form of a
15 pattern, such as dots or lines.

In one embodiment the pressure distributing element has inherent adhesive properties.

The device may be covered on the non-skin-contacting surface with a top layer, e.g. a foam, a non-woven, or a film, such as a polyurethane film. The layer will
20 enhance the strength of the dressing as well as it may serve as a barrier for the wound exudate. Further, the top layer may reduce the friction of the dressing.

In one embodiment of the invention the top layer extends beyond the edge of the pressure distributing element defining a flange around the dressing. The flange may optionally be covered with an adhesive.

The dressing may also comprise a protective cover or release liner. It does not
5 need to have the same contour as the dressing, e.g. a number of dressings may be attached to a larger sheet of protective cover. The protective cover is not present during the use of the dressing of the invention and is therefore not an essential part of the invention.

In one embodiment of the invention the dressing further comprises a pressure
10 indicator. The pressure indicator may be visible from the distal side of the dressing, when in use, said pressure indicator showing a durable change after having been exposed to a pressure above a defined level.

The indicator may be dispersed in an adhesive.

In one embodiment of the invention the indicator is incorporated in a film.

15 The indicator is preferably capable of producing a colour change. Alternatively, the indicator may create a visible change by changing solubility, and in this way change form e.g. clear to opaque.

In another embodiment of the invention the indicator may be in the form of a pressure indicating film, preferably in the form of a mono- or bilayer film.

20 The indicator may be in the form of microcapsules. These microcapsules may be coated on the dressing or a film or they may be homogeneously dispersed as

discrete particles in a matrix, such as an adhesive, absorbent or pressure distributing element.

The incorporation of a pressure indicator renders it possible for the patient or the health care person, to monitor the points of critical pressure in the area around
5 the wound without removing the dressing.

The pressure indicator may be provided in a form either having gradual pressure indication properties or the indicator may have a critical pressure level, above which the indicator will develop a visual indication.

Furthermore, the dressing of the invention may comprise a "non touch" grip
10 known per se for applying the dressing to the skin without touching the adhesive layer. Such a non-touch grip is not present after application of the dressing.

The dressing according to the invention may comprise wound healing associated indicator(s) such as indicators of pH, partial pressure of O₂, temperature, radical mechanisms or biotechnological assays, e.g. indicating formation of collagen.

15 It is also advantageous that a dressing according to the invention comprises wound healing associated indicator(s) or similar device for treatment or prophylaxis of formation of wounds and/or skin abnormalities.

This opens for a combined medical treatment of the wound and an easy and sterile application of the active ingredients, e.g. by incorporating active ingredients such as a cytokine such as growth hormone or a polypeptide growth factor
20 giving rise to the incorporation of such active substances in a form being apt to local application in a wound in which the medicament may exercise its effect on the wound, other medicaments such as bacteriostatic or bactericidal compounds,

e.g. iodine, iodopovidone complexes, chloramine, chlorohexidine, silver salts such as sulphadiazine, silver nitrate, silver acetate, silver lactate, silver sulphate, silver-sodium-thiosulphate or silver chloride, zinc or salts thereof, metronidazol, sulpha drugs, and penicillins, tissue-healing enhancing agents, e.g. RGD tripeptides and the like, proteins, amino acids such as taurine, vitamins such ascorbic acid, enzymes for cleansing of wounds, e.g. pepsin, trypsin and the like, proteinase inhibitors or metalloproteinase inhibitors such as Illostat or ethylene diamine tetraacetic acid, cytotoxic agents and proliferation inhibitors for use in for example surgical insertion of the product in cancer tissue and/or other therapeutic agents which optionally may be used for topical application, pain relieving agents such as lidocaine or chinchocaine, emollients, retinoids or agents having a cooling effect which is also considered an aspect of the invention.

The invention also relates to the use of a dressing comprising a pressure indicator being visible from the distal side of the dressing, when in use for indicating a critical pressure impact to a body part.

The invention relates further to a method of indicating a critical pressure level to a body part, comprising applying a dressing comprising a pressure indicator being visible from the distal side of the dressing, when in use, and after a period of use, inspecting the dressing and detecting an indication of critical pressure.

20 DETAILED DESCRIPTION OF THE DRAWINGS

An embodiment of the invention is shown in Figure 1. In this embodiment, a zone of absorbing material (1) surrounded by a pressure distributing material (2). A pressure indicator may be homogeneously dispersed in the pressure distributing material.

In Figure 2 is shown a preferred embodiment of the invention, with a zone of absorbent material (1) and a pressure distributing element (2). In this embodiment the absorbent material is located near the edge of the dressing. By placing the pressure distributing material here a more open structure is achieved. When
5 applied to the plantar of the foot with the absorbent element pointing towards the toes, the large zone of the pressure distributing element will be the first zone to be exposed to pressure.

In Figure 3 is shown a cross-section of an embodiment of the invention, with a zone of absorbent element (1) and a pressure distributing element (2). The
10 absorbent element extends partly through the pressure distributing element. On the distal side of the absorbing element is a pressure indicating film (8). The edges of the dressing are bevelled or rounded to enhance the comfort for the user.

In Figure 4 is shown another embodiment of the invention in which the surface of
15 the dressing not contacted with the skin is covered by a top layer (3). The top layer (3) may enhance the mechanical strength of the dressing. The top layer may be a pressure indicating film. The absorbent element (1) extends through the pressure distributing element (2).

In Figure 5 is shown a cross-section of the same embodiment of the invention
20 with one absorbing element (1) at the skin-contacting surface, and on top of the absorbing element is a super absorber (4). A top layer (3) is covering the non-skin-facing surface of the dressing. The top layer may comprise a pressure indicator.

In Figure 6 is shown another embodiment of the invention in which the edges are
25 not bevelled, with a top layer (3) on one side and a layer of an adhesive (5) on

the skin-facing side. A pressure indicator may be homogeneously dispersed as discrete particles in the adhesive (5).

Figure 7 is showing an embodiment of the invention in which the top layer (3) is elongated to extend beyond the pressure distributing element (2). On the
5 elongated part of the layer (6) an adhesive (7) is applied, essentially making the concept an island dressing, with an adhesive flange and a non-adhesive centre part. A pressure indicator may be incorporated in the top layer, pressure distributing element or absorbing element.

In Figure 8 is shown an embodiment of the invention, with a zone of absorbent
10 material (1) and a pressure distributing element (2). Like in Figure 2, the absorbent material is located near the edge of the dressing. Indentations (9) in the form of holes or dots are made the pressure distributing element. The presence of the indentations will provide more flexibility to the dressing and, depending on the depths of the indentations they may also serve as diffusion points. The indenta-
15 tions may penetrate the pressure distributing material but not the top layer, if such is present.

CLAIMS

1. A pressure relieving dressing comprising an absorbing element and a substantially non-absorbing pressure distributing element, characterised in that the absorbent element constitutes a part of a proximal skin contacting surface, said
5 absorbing element being encircled by the pressure distributing element constituting the remaining part of the surface of the dressing to be in contact with the skin.
2. A dressing according to claim 1, characterised in that the pressure distributing element is an elastomer.
- 10 3. A dressing according to claim 2, characterised in that the elastomer comprises a synthetic polymers such as silicones, polyurethanes, elastomeric copolymers or hydrophobic foams with designed properties or is a natural polymer such as natural rubber.
4. A dressing according to any of claims 1-3, characterised in that the absorbent
15 element comprises a hydrophilic foam, such as polyurethane, silicone, styrene-butadiene, styrene-isoprene or a surface coated polyethylene, or water soluble or gelling biopolymers such as polysaccharides, e.g. alginates, polyvinylpyrrolidone gels or hydrocolloids.
5. A dressing according to any of claims 1-4, characterised in that the surface
20 opposite the skin-contacting surface of the dressing is covered by a top layer.
6. A dressing according to any of claims 1-5, characterised in that the absorbent element extends through the pressure distributing element.

7. A dressing according to any of claims 1-5, characterised in that the absorbent element extend partly through the pressure distributing element.
8. A dressing according to any of claims 1-7, characterised in that the absorbent elements is situated at excentrically with respect to the pressure distributing
5 element.
9. A pressure relieving dressing comprising an absorbing element and a substantially non-absorbing pressure distributing element, characterised in that the absorbent element constitutes a part of a proximal skin contacting surface, said absorbing element being situated at the border of the pressure distributing
10 element constituting the remaining part of the surface of the dressing to be in contact with the skin.
10. A dressing according to any of claims 1-9, characterised in that the dressing comprises a pressure indicator.
11. A dressing according to any of claims 1-10, characterised in that the absorb-
15 ent element comprises a pharmaceutical or antimicrobial agent.
12. A dressing according to any of claims 1-11, characterised in that the surface of the dressing to be brought in contact with the skin shows adhesive properties.

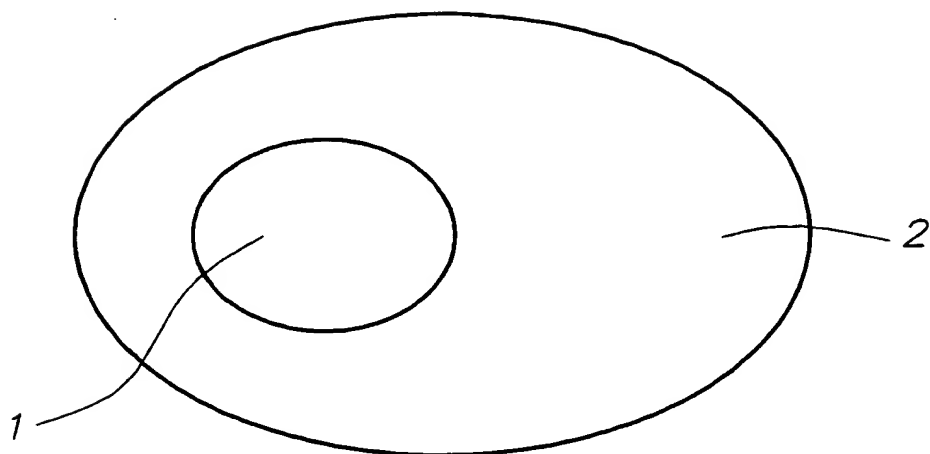


Fig. 1

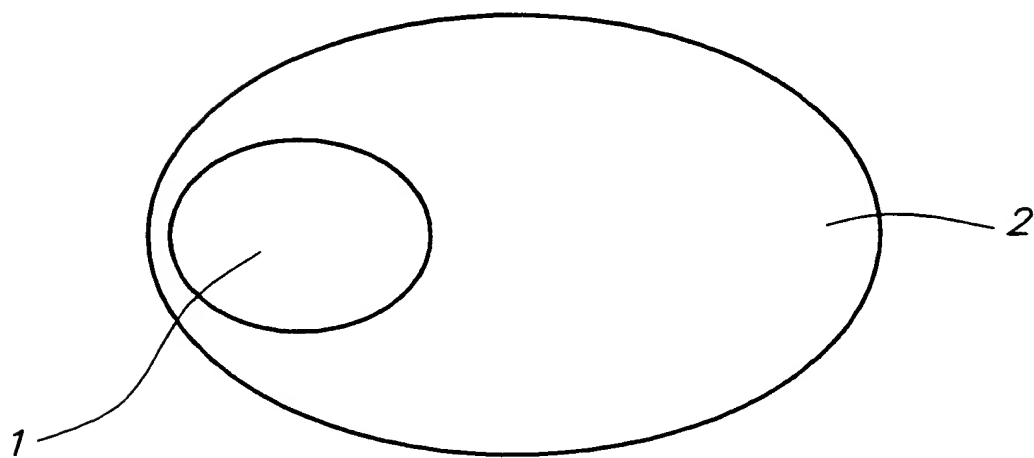
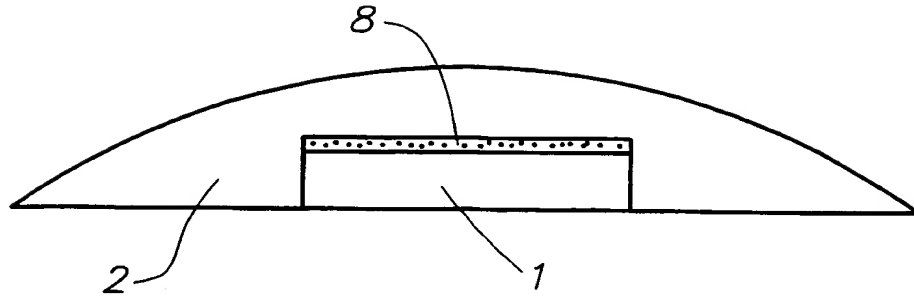
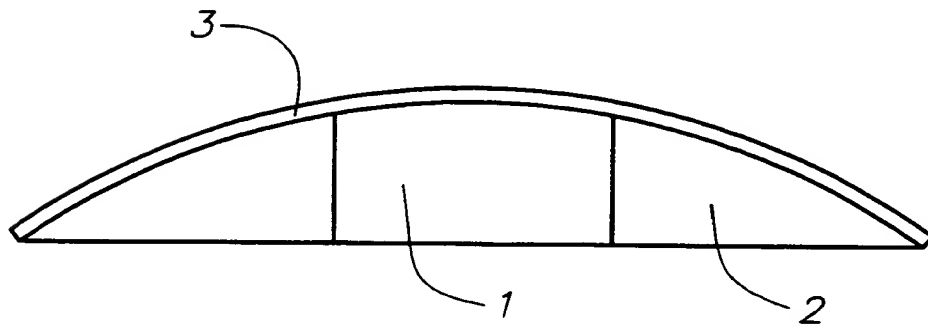
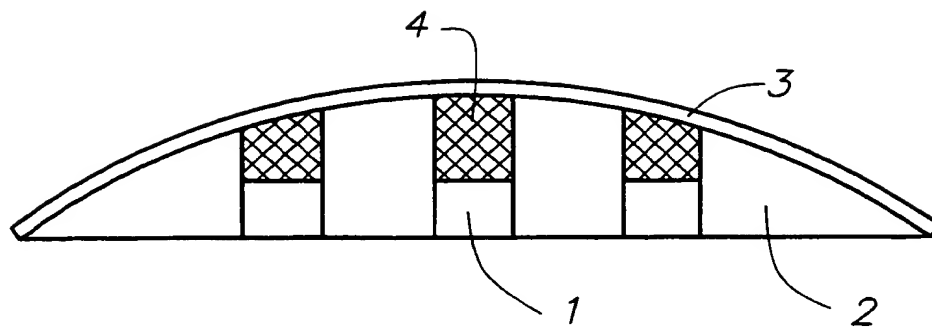
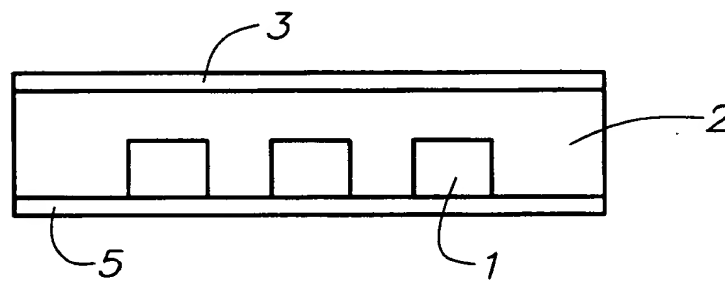
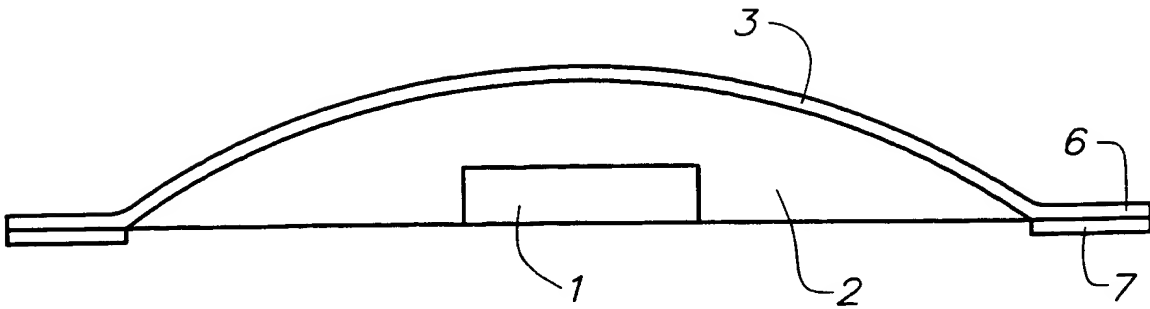
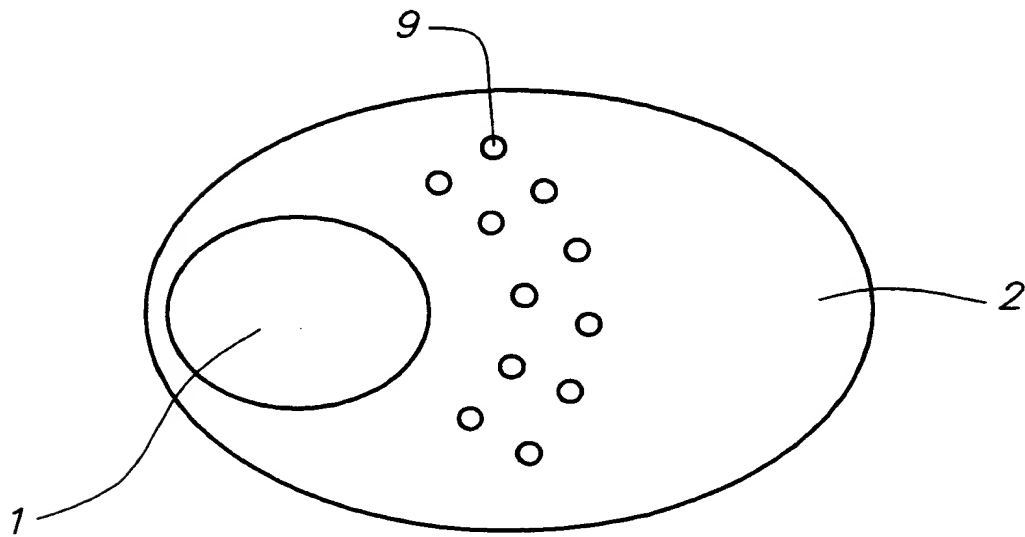


Fig. 2

*Fig. 3**Fig. 4*

*Fig. 5**Fig. 6*

*Fig. 7**Fig. 8*

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year)

20 November 2000 (20.11.00)

International application No.

PCT/DK00/00168

Applicant's or agent's file reference

99011-WO

International filing date (day/month/year)

06 April 2000 (06.04.00)

Priority date (day/month/year)

07 April 1999 (07.04.99)

Applicant

LARSEN, Truels, Sterm et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

17 October 2000 (17.10.00)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was



was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

R. E. Stoffel

Telephone No.: (41-22) 338.83.38

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference

(if desired) (12 characters maximum) 99011-WO

Box No. I TITLE OF INVENTION

A pressure relieving dressing

Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark

☐ This person is also inventor.

Telephone No.

+45 49 11 11 11

Facsimile No.

+45 49 11 15 55

Teleprinter No.

41.175 cinter

State (that is, country) of nationality:

DK

State (that is, country) of residence:

DK

This person is applicant for the purposes of:

☐ all designated States

☒ all designated States except the United States of America

☐ the United States of America only

☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

LARSEN, Truels Sterm
Frederiksborgvej 193B, 1th
DK-2400 Copenhagen NV

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

DK

State (that is, country) of residence:

DK

This person is applicant for the purposes of:

☐ all designated States

☐ all designated States except the United States of America

☒ the United States of America only

☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:

☐ agent

☒ common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark
Att.: Patent Department, Kim Nilausen

Telephone No.

+45 49 11 11 11

Facsimile No.

+45 49 11 18 49

Teleprinter No.

41.175 cinter

☐ Address for correspondence: Mark this check-box where no agent or common representative has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

OLSEN, Henrik
Egebjergtoften 75
DK-2750 Ballerup
Denmark

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:
DK

State (that is, country) of residence:
DK

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

Regional Patent

- ☒ **AP** ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ **EA** Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP** European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA** OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- | | |
|---|--|
| <input checked="" type="checkbox"/> AE United Arab Emirates | <input checked="" type="checkbox"/> LR Liberia |
| <input checked="" type="checkbox"/> AL Albania | <input checked="" type="checkbox"/> LS Lesotho |
| <input checked="" type="checkbox"/> AM Armenia | <input checked="" type="checkbox"/> LT Lithuania |
| <input checked="" type="checkbox"/> AT Austria and Utility Model | <input checked="" type="checkbox"/> LU Luxembourg |
| <input checked="" type="checkbox"/> AU Australia | <input checked="" type="checkbox"/> LV Latvia |
| <input checked="" type="checkbox"/> AZ Azerbaijan | <input checked="" type="checkbox"/> MA Morocco |
| <input checked="" type="checkbox"/> BA Bosnia and Herzegovina | <input checked="" type="checkbox"/> MD Republic of Moldova |
| <input checked="" type="checkbox"/> BB Barbados | <input checked="" type="checkbox"/> MG Madagascar |
| <input checked="" type="checkbox"/> BG Bulgaria | <input checked="" type="checkbox"/> MK The former Yugoslav Republic of Macedonia |
| <input checked="" type="checkbox"/> BR Brazil | |
| <input checked="" type="checkbox"/> BY Belarus | <input checked="" type="checkbox"/> MN Mongolia |
| <input checked="" type="checkbox"/> CA Canada | <input checked="" type="checkbox"/> MW Malawi |
| <input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein | <input checked="" type="checkbox"/> MX Mexico |
| <input checked="" type="checkbox"/> CN China | <input checked="" type="checkbox"/> NO Norway |
| <input checked="" type="checkbox"/> CR Costa Rica | <input checked="" type="checkbox"/> NZ New Zealand |
| <input checked="" type="checkbox"/> CU Cuba | <input checked="" type="checkbox"/> PL Poland |
| <input checked="" type="checkbox"/> CZ Czech Republic and Utility Model | <input checked="" type="checkbox"/> PT Portugal |
| <input checked="" type="checkbox"/> DE Germany and Utility Model | <input checked="" type="checkbox"/> RO Romania |
| <input checked="" type="checkbox"/> DK Denmark and Utility Model | <input checked="" type="checkbox"/> RU Russian Federation |
| <input checked="" type="checkbox"/> DM Dominica | <input checked="" type="checkbox"/> SD Sudan |
| <input checked="" type="checkbox"/> EE Estonia and Utility Model | <input checked="" type="checkbox"/> SE Sweden |
| <input checked="" type="checkbox"/> ES Spain | <input checked="" type="checkbox"/> SG Singapore |
| <input checked="" type="checkbox"/> FI Finland and Utility Model | <input checked="" type="checkbox"/> SI Slovenia |
| <input checked="" type="checkbox"/> GB United Kingdom | <input checked="" type="checkbox"/> SK Slovakia and Utility Model |
| <input checked="" type="checkbox"/> GD Grenada | <input checked="" type="checkbox"/> SL Sierra Leone |
| <input checked="" type="checkbox"/> GE Georgia | <input checked="" type="checkbox"/> TJ Tajikistan |
| <input checked="" type="checkbox"/> GH Ghana | <input checked="" type="checkbox"/> TM Turkmenistan |
| <input checked="" type="checkbox"/> GM Gambia | <input checked="" type="checkbox"/> TR Turkey |
| <input checked="" type="checkbox"/> HR Croatia | <input checked="" type="checkbox"/> TT Trinidad and Tobago |
| <input checked="" type="checkbox"/> HU Hungary | <input checked="" type="checkbox"/> TZ United Republic of Tanzania |
| <input checked="" type="checkbox"/> ID Indonesia | <input checked="" type="checkbox"/> UA Ukraine |
| <input checked="" type="checkbox"/> IL Israel | <input checked="" type="checkbox"/> UG Uganda |
| <input checked="" type="checkbox"/> IN India | <input checked="" type="checkbox"/> US United States of America |
| <input checked="" type="checkbox"/> IS Iceland | |
| <input checked="" type="checkbox"/> JP Japan | <input checked="" type="checkbox"/> UZ Uzbekistan |
| <input checked="" type="checkbox"/> KE Kenya | <input checked="" type="checkbox"/> VN Viet Nam |
| <input checked="" type="checkbox"/> KG Kyrgyzstan | <input checked="" type="checkbox"/> YU Yugoslavia |
| <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea | <input checked="" type="checkbox"/> ZA South Africa |
| | <input checked="" type="checkbox"/> ZW Zimbabwe |
| <input checked="" type="checkbox"/> KR Republic of Korea | Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet: |
| <input checked="" type="checkbox"/> KZ Kazakhstan | <input checked="" type="checkbox"/> DZ Algeria |
| <input checked="" type="checkbox"/> LC Saint Lucia | <input checked="" type="checkbox"/> AG Antigua & Barbuda |
| <input checked="" type="checkbox"/> LK Sri Lanka | |

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *Confirmation (including fees) must reach the receiving Office within the 15-month time limit.*

Box No. VI PRIORITY CLAIM		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application: regional Office	international application: receiving Office
item (1) 7 April 1999	PA 1999 00463	DK		
item (2) 7 April 1999	PA 1999 00464	DK		
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): (1) + (2)

* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.

Box No. VII INTERNATIONAL SEARCHING AUTHORITY			
Choice of International Searching Authority (ISA) <small>(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):</small>		Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):	
ISA / EP		Date (day/month/year) 27 October 1999	Number DK 99/00045
		Country (or regional Office) DK	

Box No. VIII CHECK LIST; LANGUAGE OF FILING	
This international application contains the following number of sheets: request : 4 description (excluding sequence listing part) : 16 claims : 2 abstract : 1 drawings : 4 sequence listing part of description : Total number of sheets : 27	This international application is accompanied by the item(s) marked below: 1. <input checked="" type="checkbox"/> fee calculation sheet 2. <input type="checkbox"/> separate signed power of attorney 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: 4. <input type="checkbox"/> statement explaining lack of signature 5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): 6. <input type="checkbox"/> translation of international application into (language): 7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material 8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form 9. <input checked="" type="checkbox"/> other (specify): Copy of ITS Report DK 99/00045
Figure of the drawings which should accompany the abstract: 4	Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT	
<small>Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).</small>	
Coloplast A/S	
	
NIELSEN, Peter Sylvest, Research and Development Manager	
	
LARSEN, Truels Sterm, Inventor	OLSEN, Henrik, Inventor

For receiving Office use only	
1. Date of actual receipt of the purported international application:	2. Drawings: <input type="checkbox"/> received: <input type="checkbox"/> not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority (if two or more are competent): ISA/	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid.

Date of receipt of the record copy by the International Bureau:	For International Bureau use only
---	-----------------------------------

PCT

FEE CALCULATION SHEET Annex to the Request

For receiving Office use only

International application No.

Applicant's or agent's
file reference 99011-WO

Date stamp of the receiving Office

Applicant
Coloplast A/S

CALCULATION OF PRESCRIBED FEES

- | | | |
|--------------------|----------|---|
| 1. TRANSMITTAL FEE | 1,500.00 | T |
| 2. SEARCH FEE | 7,090.00 | S |

International search to be carried out by EP
(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

The international application contains 27 sheets.

first 30 sheets 3,060.00 b1

x = b2

remaining sheets additional amount

Add amounts entered at b1 and b2 and enter total at B 3,060.00 B

Designation Fees

The international application contains 85 designations.

85 x 660.00 = 5,280.00 D

number of designation fees payable (maximum 8) amount of designation fee

Add amounts entered at B and D and enter total at I 8,340.00 I

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

- | | | |
|--|---|---|
| 4. FEE FOR PRIORITY DOCUMENT (if applicable) | - | P |
|--|---|---|

- | | |
|-----------------------|-----------|
| 5. TOTAL FEES PAYABLE | 16,930.00 |
|-----------------------|-----------|

Add amounts entered at T, S, I and P, and enter total in the TOTAL box

TOTAL

☐ The designation fees are not paid at this time.

MODE OF PAYMENT

- | | | |
|--|---|---|
| <input type="checkbox"/> authorization to charge deposit account (see below) | <input type="checkbox"/> bank draft | <input type="checkbox"/> coupons |
| <input checked="" type="checkbox"/> cheque | <input type="checkbox"/> cash | <input type="checkbox"/> other (specify): |
| <input type="checkbox"/> postal money order | <input type="checkbox"/> revenue stamps | |

DEPOSIT ACCOUNT AUTHORIZATION (this mode of payment may not be available at all receiving Offices)

The RO ☐ is hereby authorized to charge the total fees indicated above to my deposit account.

☐ (this check-box may be marked only if the conditions for deposit accounts of the receiving Office so permit) is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

☐ is hereby authorized to charge the fee for preparation and transmittal of the priority document to the International Bureau of WIPO to my deposit account.

Deposit Account No.

Date (day/month/year)

Signature

DEN DANSKE BANK
Holmens Kanal Afdeling
Holmens Kanal 2
1090 København K
Telefon 33 44 00 00

Espergærde den 5. april 2000

Kroner sekstentusindnihundredtreti---

Til

Patent- og Varemærkestyrelsen
Helgeshøj Alle 81
2630 Taastrup



Coloplast

Betal denne check med kr. 16.930,00

Coloplast A/S

Check nr.

0018257

Regnr.

00000000

Kode

1600

Kontonr.

3001311411820

Parti nr.

Nr 0018257

vor ref 99011 W0

Udgående check
er i besiddelse af
overstående ordre

Coloplast A/S
Hovedvej 1
DK-3050 Humlebæk
Danmark



Coloplast

PATENT COOPERATION TREATY

PATENTAFDELINGEN From the INTERNATIONAL BUREAU

PCT 13 JUNI 2000

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

COLOPLAST A/S
Att: Patent Department,
Nilausen, Kim
Holtedam 1
DK-3050 Humlebaek
DANEMARKAMS
14.06.2000

Date of mailing (day/month/year) 02 June 2000 (02.06.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 99011-WO	
International application No. PCT/DK00/00168	International filing date (day/month/year) 06 April 2000 (06.04.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 07 April 1999 (07.04.99)
Applicant COLOPLAST A/S et al	

- The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR" in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
- An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
07 April 1999 (07.04.99)	PA 1999 00463	DK	12 May 2000 (12.05.00)
07 April 1999 (07.04.99)	PA 1999 00464	DK	12 May 2000 (12.05.00)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer Max Germeil Telephone No. (41-22) 338.83.38
--	--

REC'D 01 MAR 2001

WIPO

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference 99011-WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/DK00/00168	International filing date (day/month/year) 06/04/2000	Priority date (day/month/year) 07/04/1999
International Patent Classification (IPC) or national classification and IPC A61F13/02		
Applicant COLOPLAST A/S		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 4 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 16 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 17/10/2000	Date of completion of this report 27.02.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Auer, H Telephone No. +49 89 2399 2054 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK00/00168

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

Description, pages:

1-14 as received on 05/02/2001 with letter of 05/02/2001

Claims, No.:

1-12 as received on 05/02/2001 with letter of 05/02/2001

Drawings, sheets:

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK00/00168

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-12
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-12
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-12
	No:	Claims	

2. Citations and explanations
see separate sheet

ad V:

1. Most relevant prior art document is DE-A-3539533, which is cited in the description and which discloses a pressure relieving dressing with an absorbent element and a non-absorbing pressure distributing element.

The problem of the invention is to provide a dressing being capable of both handling wound exudates and at the same time relieving both static and dynamic pressure.

The solution is given by the combination of features of claim 1, i.e. in particular that the absorbent element is situated eccentrically with respect to the pressure distributing element.

There is no hint in DE-A-3539533 for this solution nor in the other documents cited in the search report which disclose only technological background.
Claim 1 is, therefore, in line with Articles 33(2) and (3) PCT.

2. The subject-matter of the dependent claims contain further embodiments of the invention and is also in combination with the independent claims novel and inventive (Articles 33(2) and (3) PCT).

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 99011-W0	<div style="display: flex; justify-content: space-between;"> <div> FOR FURTHER ACTION </div> <div> <small>see Notification of Transmittal of International Search Report (Form PCT/ISA 220) as well as, where applicable, item 5 below.</small> </div> </div>
International application No. PCT/DK 00/00168	<div style="display: flex; justify-content: space-between;"> <div> International filing date (<i>day/month/year</i>) 6 April 2000 </div> <div> (Earliest) Priority Date (<i>day/month/year</i>) 7 April 1999 </div> </div>
Applicant Coloplast A/S et al.	

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (See Box I).

2. ☐ Unity of invention is lacking (See Box II).

3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing

☐ filed with the international application.
☐ furnished by the applicant separately from the international application,

☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.

☐ transcribed by this Authority.

4. With regard to the title, ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☐ the text is approved as submitted by the applicant.
☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is:

Figure No. 4

☒ as suggested by the applicant.

☐ None of the figures.

☐ because the applicant failed to suggest a figure.
☐ because this figure better characterizes the invention.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

A pressure relieving dressing comprising an absorbing element and a substantially non-absorbing pressure distributing element, in which the absorbent element constitutes a part of a proximal skin contacting surface, said absorbing element being encircled by the pressure distributing element or being situated at the border of the pressure distributing element constituting the remaining part of the surface of the dressing to be in contact with the skin rendering it possible to obtain an effective and durable dressing suitable for both wound healing and prophylaxis of pressure ulcers.

INTERNATIONAL SEARCH REPORT

International Application No

PCT 00/00168

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F13/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 35 39 533 A (LIEDTKE PHARMED GMBH) 14 May 1987 (1987-05-14) figures 1-4	1-12
A	GB 842 847 A (SCHOLL MFG CO LTD) 27 July 1960 (1960-07-27) page 2, line 74 - line 84; figures 1-4	1-12
A	WO 93 01777 A (MALLOUL LYDIE) 4 February 1993 (1993-02-04) figures 1-4	1-12

☐

Further documents are listed in the continuation of box C.

☒

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

22 June 2000

Date of mailing of the international search report

28 AUG 2000

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I. Falk/AB

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/00/00168

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 3539533 A	14-05-1987	NONE	
GB 842847 A		CH 378465 A US 2918062 A	22-12-1959
WO 9301777 A	04-02-1993	FR 2679129 A AU 2388692 A EP 0557473 A	22-01-1993 23-02-1993 01-09-1993